

**CERTIFICATE OF MAILING**

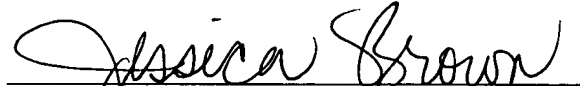
I hereby certify that on August 10, 2001, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231.

37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10

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\_\_\_\_\_  
Jessica Brown

**Applicant:**

**Serial No.:**

**Filed:**

**Title:**



**Examiner:**

**Group Art Unit:**

**Atty. Docket No.:**

**Wesley Paul Durkalski**

**09/836,653**

**April 17, 2001**

**SYSTEM AND METHOD FOR  
ENABLING AN UNTRAINED OR  
NOVICE END-USER TO RAPIDLY  
BUILD CLINICAL TRIALS DATA  
MANAGEMENT SYSTEMS**

**COMPLIANT WITH ALL  
APPROPRIATE REGULATORY  
GUIDANCES**

**Not Yet Assigned**

**2171**

**20207-11**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS, MAILED JUNE 12, 2001**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Notice to file Corrected Application Papers, mailed June 12, 2001, Applicant has prepared corrected drawings sheets in compliance with 37 CFR 1.84. Accordingly, Applicant submits the following papers:

- ☒ This Response to Notice to File Corrected Application Papers;
- ☒ A Copy of the Notice to File Corrected Application Papers, Part 2;
- ☒ The Application filed April 17, 2001, including Ten (10) Replacement Drawing Sheets (Figs. 1-10).

Additionally, Applicant submits for consideration in this case:

- ☒ Request for Corrected Filing Receipt;
- ☒ Information Disclosure Statement;
- ☒ Form PTO-1449 with copies of cited references; and
- ☒ Return acknowledgement postcard.

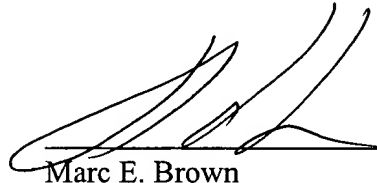
09/836,653

Applicant: Wesley Paul Durka  
Serial No.: 09/836,653  
Group Art Unit: 2171

PATENT  
Attorney Docket: 20207-11

Please charge any fees associated with this filing or credit overpayment to Deposit  
Account No. 16-2230. A duplicate of this sheet is enclosed.

Dated: August 10, 2001

  
\_\_\_\_\_  
Marc E. Brown  
Reg. No. 28,590

**OPPENHEIMER WOLFF & DONNELLY LLP**  
2029 Century Park East, 38<sup>th</sup> Floor  
Los Angeles, California 90067-3024  
Telephone: 310.788.5000  
Fax: 310.788.5100

09/836653-081701


AA

I CERTIFY THAT ON AUGUST 10, 2001, WHICH IS THE DATE I AM SIGNING THIS CERTIFICATE, THIS CORRESPONDENCE AND IDENTIFIED ENCLOSURES ARE BEING DEPOSITED IN THE UNITED STATES POSTAL SERVICE, POSTAGE PAID FIRST CLASS, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231.



Receipt #4

**PATENT**  
**Docket No. 20207-11**

  
JESSICA BROWN

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Wesley Paul Durkalski

For: System and Method for Enabling an  
Untrained or Novice End-User to Rapidly Build  
Clinical Trials Data Management Systems  
Compliant With All Appropriate Regulatory  
Guidelines

Serial No.: 09/836,653

Filed: April 17, 2001

**REQUEST FOR CORRECTED FILING RECEIPT**

Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, D.C. 20231

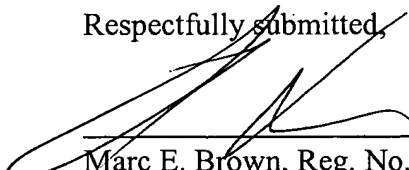
Sir:

1. Attached is a copy of the official filing receipt received from the Patent & Trademark Office in the above application for which issuance of a corrected filing receipt is respectfully requested.

2. There is an error in title of the invention. The word "cilinical" should be changed to "clinical" as follows: "Systems and methods for enabling an untrained or novice end-user to rapidly build clinical trials data management systems compliant with all appropriate regulatory guidances."

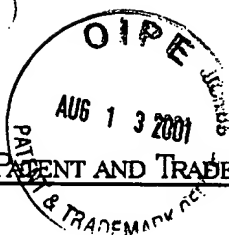
Respectfully submitted,

Dated: August 10, 2001

  
Marc E. Brown, Reg. No. 28,590  
OPPENHEIMER WOLFF & DONNELLY LLP  
2029 Century Park East, 38th Floor  
Los Angeles, California 90067-3024  
Phone: (310) 788-5000 \* Fax: (310) 788-5100



**UNITED STATES PATENT AND TRADEMARK OFFICE**



COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/836,653	04/17/2001	2171	395	20207-11	10	20	4

**CONFIRMATION NO. 7384**

**FILING RECEIPT**



\*OC00000006170660\*

OPPAENHEIMER WOLFF & DONNELLY LLP  
ATTN: MARC E. BROWN, ESQ.  
38TH FLOOR  
2029 CENTURY PARK EAST  
LOS ANGELES, CA 90067

Date Mailed: 06/12/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

**Applicant(s)**

Wesley Paul Durkalski, Charleston, SC;

**Domestic Priority data as claimed by applicant**

THIS APPLN CLAIMS BENEFIT OF 60/197,648 04/17/2000

**Foreign Applications**

If Required, Foreign Filing License Granted 06/11/2001

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

**\*\* SMALL ENTITY \*\***

**Title**

Systems and methods for enabling an untrained or novice end-user to rapidly build clinical trials data management systems compliant with all appropriate regulatory guidances

**DOCKETED**

JUN 15 2001

**OWD-LA**

**OWD**

JUN 15 2001

**RECEIVED**

*clinical*

**Preliminary Class**

707

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**Data entry by : DUONG, MICHAEL**

**Team : OIPE**

**Date: 06/12/2001**





**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15 (b).

**PLEASE NOTE the following information about the Filing Receipt:**

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 500 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

Assistant Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, DC 20231



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/836,653	04/17/2001	Wesley Paul Durkalski	20207-11

CONFIRMATION NO. 7384

## FORMALITIES LETTER



\*OC00000006170661\*

OPPAENHEIMER WOLFF & DONNELLY LLP  
ATTN: MARC E. BROWN, ESQ.  
38TH FLOOR  
2029 CENTURY PARK EAST  
LOS ANGELES, CA 90067

Date Mailed: 06/12/2001

## NOTICE TO FILE CORRECTED APPLICATION PAPERS

*Filing Date Granted*

This application has been accorded an Application Number and Filing Date. The application, however, is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a)

The required item(s) identified below must be timely submitted to avoid abandonment:

- Substitute drawings in compliance with 37 CFR 1.84 because:
  - drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. ( 5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch);

*A copy of this notice MUST be returned with the reply.*

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

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